K051679
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510(k) Summary of Safety and Effectiveness

Boston Scientific Corporation

iLab™ Ultrasound Imaging System

JUL 1 4 2005

Submitted By

Boston Scientific Corporation
IVUS Technology Center
47201 Lakeside Parkway
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Contact Person

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Date Prepared

July 7, 2005

Proprietary Name

iLab™ Ultrasound Imaging System

Common Name(s)

Ultrasound Diagnostic Imaging System
Ultrasonic Pulsed Doppler Imaging System (90IYN)
Ultrasonic Pulsed Echo Imaging System (90IYO)

Classification Name(s)

Ultrasonic Pulsed Doppler Imaging System 21 CFR Part 892.1550 (90IYN)
Ultrasonic Pulsed Echo Imaging System 21 CFR Part 892.1560 (90IYO)

Predicate Device

The iLab™ Ultrasound Imaging System is substantially equivalent to the following device:

Product	510(k)	Clearance Date
Galaxy® Intravascular Ultrasound System	K980851	April 22, 1998

Description of the Device

The iLab™ Ultrasound Imaging System is a combination of proprietary hardware and software that has been designed for real-time viewing of intravascular anatomies and is intended to be a basic diagnostic tool for imaging and evaluation of patients who are candidates for transluminal procedures. The iLab™ System is based on a modular and flexible architecture allowing for both mobile and stationary (installed) configurations.

The system is designed for imaging intravascular anatomies with transducer ranges of 9 to 40 MHz. The iLab™ System is also designed to be compatible with multiple Ultrasound Imaging Catheters manufactured by BSC used in different anatomies throughout the body. The system

is also supported by a MotorDrive Unit that is compatible with all existing BSC Intravascular Ultrasound (IVUS) catheter products.

The iLab™ System consists of two compact PC units (one for Image Processing and one for Data Acquisition), up to two displays, control devices, media storage devices, and a printer. The Data Acquisition PC (front-end PC) digitizes the RF Ultrasound echo, performs digital signal processing, and stores IVUS frames in a vector-based format. Once saved, the vector-based frame of data is packetized and sent over a private Local Area Network (LAN) connection onto the Image Processing PC (back-end PC) subsystem. The real-time vector data is unpacked and the frame data is converted from vector-based to raster-based frame, which can then be displayed on the primary and secondary (optional) displays.

The iLab™ System is available in two configurations: a Cart-based Configuration and an Installed Configuration. There is no *functional or electrical* difference between the Cart-Based and Installed Configurations; differences are limited to cable lengths and the location of the modules of the system.

Intended Use/Indications

The iLab™ Ultrasound Imaging System is intended for ultrasound examinations of intravascular pathology. Intravascular ultrasound is indicated in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy.

Device Technology Characteristics and Comparison to Predicate Device

The iLab™ System applies ultrasound energy through a transducer enclosed within a catheter. This ultrasound energy is directed from the catheter in the lumen of a vessel into the interior vessel wall of the patient in order to obtain a two-dimensional image of the vessel anatomy. The two-dimensional image, reconstructed from the reflected RF Ultrasound echo, can be used to evaluate the morphology of the vessel and as such potentially detect abnormalities or obstructions. Each of the technological characteristics found in the iLab™ System are identical or similar to those of the predicate device, Galaxy® Intravascular Imaging System. The iLab™ System is similar in design, function, and application to these ultrasound systems.

Non-clinical Test Results

Bench electrical safety and acoustic output safety testing demonstrate that the iLab™ System and its accessories meet or exceed performance requirements and is safe and effective for its intended use.

Bench Testing

Bench testing was performed to evaluate the performance and functionality of the iLab™ System. This testing included hardware unit-level tests, software unit-level test, and system-level tests. The results demonstrate that the device satisfies all performance and functional requirements.

Electrical Safety Testing

The iLab™ System complies with EN 60601-1 and EN 60601-1-2 standards as verified by independent test facilities. The iLab™ System software was verified and validated in accordance with applicable FDA guidance documents.

Acoustic Output Testing

Acoustic output testing for the iLab™ System is supported by acoustic output data generated with the Galaxy® System for the acoustic output requirements of the iLab™ System, pre and post submission, as required by FDA Guidance, "*Information for Manufactures Seeking Market Clearance of Diagnostic Ultrasound Systems and Transducers*", issued September 30, 1997. The component generating acoustic output on the Galaxy® and iLab™ Systems is the MotorDrive Unit. The MotorDrive Unit was tested with the Galaxy® System (predicate device) and was previously cleared by premarket notification K980851. The iLab™ System utilizes the same MotorDrive Unit.

Design reviews, unit testing, and design verification have been carried out to ensure the transmission signals of the iLab™ System are identical to those generated by the Galaxy® System. Since both the Galaxy® and iLab™ Systems are designed to use the same transducers (catheters), the signal frequency and acoustic efficiency of these transducers (catheters) will be exactly same for each system. Therefore, the final acoustic output level for the Galaxy® and the iLab™ Systems will be the same and acoustic output testing is unwarranted.

Conclusion

The iLab™ Ultrasound Imaging System utilizes the same fundamental technology and has the same intended use as the predicate device, the Galaxy® Intravascular Ultrasound Imaging System. The tests support a determination of substantial equivalence of the modified device, the iLab™ Ultrasound Imaging System to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 2005

Boston Scientific Corporation
c/o Mr. Robert Z. Phillips, Manger, Regulatory Affairs
IVUS Technology Center
47201 Lakeview Boulevard
Fremont, CA 94538

Re: K051679
iLab ™ Ultrasound Imaging System
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II (two)
Product Code: 74 DQO
Dated: June 21, 2005
Received: June 23, 2005

Dear Mr. Phillips:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

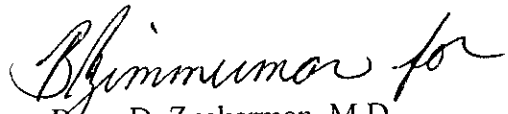
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0295 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051679

Indications for Use Statement

510(k) Number: K051679

Device Name: iLab™ Ultrasound Imaging System

Indications for Use: The iLab™ Ultrasound Imaging System is intended for ultrasound examinations of intravascular pathology. Intravascular ultrasound is indicated in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy.

Prescription Use ___X___ AND/ OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Zimmerman for

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051679